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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,805	04/24/2001	Preeti Lal	PF-0456-2 DIV	7874

27904 7590 08/06/2003

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EXAMINER
CARLSON, KAREN C

ART UNIT	PAPER NUMBER
1653	11

DATE MAILED: 08/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/841,805	LAL ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *10 and 29-44* is/are pending in the application.

4a) Of the above claim(s) *29,32,34,35,38,43 and 44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,30,31,33,36,37 and 39-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

This Office Action is in response to Paper #10, filed June 11, 2003.

Claims 1-9, 11-28, and 45-48 have been canceled. Claims 29, 32, 34, 35, 38, 34, 43, and 44 have been withdrawn from further consideration at this time by the Examiner because these Claims are drawn to non-elected inventions. Claims 10, 30, 31, 33, 36, 37, and 39-42 are currently under examination.

Priority is to January 8, 1998.

Maintenance of Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36 and 39 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 36 and 39 depend from non-elected inventions. Therefore, these claims are indefinite.

Applicants urge that upon rejoinder of the method inventions, Claims 36 and 39 will be clear. The antibody is not allowed, and therefore rejoinder will not occur. Therefore, this argument is not persuasive.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10, 30, 31, 33, 36, 37, and 39-42 are rejected under 35 U.S.C. 102(a) as being anticipated by Singleton et al. (26 August 1997; J. Cell. Sci. 110:2099-2107).

Singleton et al. teach secretory carrier membrane protein (SCAMPs) SCAMP3 having 98.1% sequence identity to SEQ ID NO:1. See Fig. 1. At page 2101, col. 1, line 14, Singleton et al. teach making antibodies to SCAMP3 using the sequence SPTEPKNYGSYSTQ, which is found within instant SEQ ID NO: 1. Given that antibodies bind epitopic structures rather than sequences per se, and the identity between SCAPM3 and SEQ ID NO: 1 is high, the antibody made by Singleton et al. will also bind polypeptides having SEQ ID NO: 1 (Claim 10, 30, 36, 39). The antibodies were in composition (Claim 31, 37, 40), and the antibodies were labeled via coupling to hemocyanin (Claim 33). Claims 41 and 42 are being considered to be anticipated as well because there appears to be no difference in the antibody made by a Fab expression library or and immunoglobulin expression library.

Singleton et al. also teach SCAMP2 having 99% sequence identity to SEQ ID NO: 3. See Fig. 1. At page 2101, col. 1, line 12, Singleton et al. teach making antibodies to SCAMP2 using the sequence QPSVEPTOPTPO, which is found within instant SEQ ID NO: 3. Given that antibodies bind epitopic structures rather than sequences per se, and the identity between SCAPM2 and SEQ ID NO: 3 is high, the antibody made by Singleton et al. will also bind polypeptides having SEQ ID NO: 3 (Claim 10, 30, 36, 39). The antibodies were in composition (Claim 31, 37, 40), and the antibodies were labeled via coupling to hemocyanin (Claim 33). Claims 41 and 42 are being considered to be anticipated as well because there appears to be no difference in the antibody made by a Fab expression library or and immunoglobulin expression library.

Claims 10, 30, 31, 33, 36, 37, and 39-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Brand et al. (1993; EMBO J. 12(10) 3753-3761).

Brand et al. teach secretory carrier membrane protein (SCAMPs) SCAMP37 having 51% sequence identity to SEQ ID NO:1. See Fig. 5a . At page 3760, col. 1, para. 1, Brand et al. teach making antibodies to SCAMP37, resulting in antibody SG7C12. Given that antibodies bind epitopic structures rather than sequences per se, and the identity between SCAMP37 and SEQ ID NO: 1 is high, the antibody made by Brand et al. will also bind polypeptides having SEQ ID NO: 1 (Claim 10, 30, 36, 39). The antibodies were in composition (Claim 31, 37, 40), and the antibodies were labeled via coupling to Affigel-Hz (para. 2; Claim 33). Claims 41 and 42 are being considered to be anticipated as well because there appears to be no difference in the antibody made by a Fab expression library or and immunoglobulin expression library.

SCAMP 37 also has 57.4% sequence identity to SEQ ID NO: 3. See Fig. 5a. At page 3760, col. 1, para. 1, Brand et al. teach making antibodies to SCAMP37, resulting in antibody SG7C12. Given that antibodies bind epitopic structures rather than sequences per se, and the identity between SCAMP37 and SEQ ID NO: 1 is high, the antibody made by Brand et al. will also bind polypeptides having SEQ ID NO: 1 (Claim 10, 30, 36, 39). The antibodies were in composition (Claim 31, 37, 40), and the antibodies were labeled via coupling to Affigel-Hz (para. 2; Claim 33). Claims 41 and 42 are being considered to be anticipated as well because there appears to be no difference in the antibody made by a Fab expression library or and immunoglobulin expression library.

Applicants present the same argument for both references. Applicants urge that because the sequences of the references are not identical to instant SEQ ID NO: 1 and NO: 3, an antibody can be made that does not bind to the reference sequences, thus overcoming the

rejections. This argument is not persuasive because the term "specifically binds" is not limited in the art as Applicants suggest.

As evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586) and Bendayan (J. Histochem. Cytochem. 1995; 43:881-886), an antibody "cross-reacts", i.e., binds to more than one protein sequence, does not mean that the antibody does not "specifically react" with both proteins. For example, Bost et al. describe antibodies which "cross-react" with IL-2 and HIV envelope protein, but establish that the binding of each protein is due to the presence of a homologous sequence in each protein in which 4 of 6 residues were identical (see entire document, but especially the Abstract and Discussion). Antibodies which bound either the HIV or IL-2 derived sequence did not cross react with irrelevant peptides (e.g., "Results, page 579).

Similarly, Bendayan characterizes the specific reactivity of a monoclonal antibody produced to human proinsulin and shows that although the antibody is highly specific; it is nevertheless able to bind to not only human proinsulin, but to proinsulin from other species and even a distinct protein, glucagon, based upon conservation of an Arg-Arg dipeptide sequence in each of these molecules (see entire document). Bendayan concludes that "an antibody directed against such a sequence, although still yielding specific labeling, could reveal different molecules not related to the original antigen" (page 886, last paragraph).

Abaza et al. (Journal of Protein Chemistry, Vol. 11, No. 5, 1992, pages 433-444) teaches single amino acid substitutions outside the antigenic site on a protein effect antibody binding; thus it is also essential to provide some guidance as to the identity of the flanking sequences of a fragment of a polypeptide of interest. Further, Li et al. (Proc. Natl. Acad. Sci. USA 77: 3211-3214, 1980) disclose that dissociation of immunoreactive from other biological activities when constructing analogs (see entire document).

Thus in the absence of sufficient guidance to a particular epitope and the structural context in which the epitope is found; it is highly unpredictable which other isolated polypeptides comprising a variant sequence of SEQ ID NO:2 would maintain the relevant antibody epitope(s).

See also U.S. Pat. No. 6210670 (Berg) entitled "Cross-Reacting Monoclonal Antibodies Specific for E-Selectin and P-selectin".

Applicant's argument attempts to limit the term "specifically reacts" in a manner inconsistent with the well-known and art-recognized specificity of antibody interaction with epitopes defined by particular amino acid sequences. Consequently, it was well known in the art at the time the invention was made that antibody binding of distinct proteins was indeed specific.

No Claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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July 28, 2003

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER